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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/869,630      | 09/21/2001  | Peter Knox           | PA 9847             | 5704             |

22840 7590 06/03/2003

AMERSHAM BIOSCIENCES  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

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| EXAMINER |
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LAM, ANN Y

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/869,630

Applicant(s)

KNOX ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09/21/01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger et al., 6,090,800. Unger et al. disclose an in vitro method (see column 5, line 64; column 6, line 17; column 10, line 9; column 12, line 40; and column 82, line 66) which comprises labeling a biological molecule with hyperpolarized xenon (see column 57, line 24), and observing a magnetic resonance spectrum (NMR) and/or NMR image (see column 55, lines 43-47; and see column 82, line 66 – column 83, line 5) of the hyperpolarized xenon in the environment of the biological molecule.

As to claim 2, the molecule is an assay reagent taking part in an assay method (see column 93, lines 65-66; and column 98, lines 44-54.)

As to claim 3, the assay is an immunoassay, see column 42, lines 17-64.

As to claim 4, the assay is a binding assay, (see column 93, lines 65-66; and column 98, lines 44-54.)

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As to claim 5, the molecule is a peptide or a protein, see column 23, lines 32-53.

As to claim 6, the hyperpolarized xenon is enriched at a level of 40% or more (see column 4, lines 62-67.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al., 6,090,800. Unger discloses the invention substantially as claimed (see above), except for the degree of hyperpolarisation being 8% or more; or the method being performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs; or the pressure of the xenon gas being at least 5 bar.

As to claim 7, it would have been obvious matter of design choice to modify the Unger reference by having the degree of hyperpolarisation be 8% or more since applicant has not disclosed that having the this percentage of hyperpolarisation solves any stated problem or is for any particular purpose and it appears that this percentage of hyperpolarisation would perform equally well as at a hyperpolarisation of a slightly different percentage (see for example column 57, lines 23-25.)

As to claim 8, it would have been obvious matter of design choice to modify the Unger reference by performing the method in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs since applicant has not disclosed that the solvent in this viscosity solves any stated problem or is for any particular purpose and it appears that this viscosity would perform equally well as at a slightly different viscosity (see for example, column 31, lines 43-45.)

As to claim 9, it would have been obvious matter of design choice to modify the Unger reference such that the pressure of the xenon gas is at least 5 bar since applicant has not disclosed that pressure at this level solves any stated problem or is for any particular purpose and it appears that this pressure would perform equally well as at a slightly different pressure (see for example, column 31, lines 26-31.)

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-TH 8-6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.  
June 2, 2003

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
06/02/03